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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-0010]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposures (BD-STEPS) (formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB # 0920-0010, Expiration 04/30/2015) - Revision - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects currently covering three counties in Metropolitan Atlanta.

Since 1997, CDC has funded case-control studies of major birth defects that utilize existing birth defect surveillance registries (including MACDP) to identify cases and study birth defects causes in participating states/municipalities across the United States.

BD-STEPS is a case-control study that is similar to the previous CDC-funded birth defects case-control study, NBDPS, which stopped interviewing participants in 2013. As with NBDPS, control infants will be randomly selected from birth certificates or birth hospital records; mothers of case and control infants will be interviewed using a computer-assisted telephone interview.

The BD-STEPS interview takes approximately forty-five minutes to complete. A maximum of 275 interviews are planned per year per center, 200 cases and 75 controls. With seven centers planned, the maximum interview burden for all centers combined would be approximately 1,444 hours. As with NBDPS,

parents in BD-STEPS will be asked to collect deoxyribonucleic acid(DNA) samples from themselves and their infants. The collection of saliva cells by the mother, father and infant takes about 15 minutes per person. For the infant sample, the parent will rub long-handled sponges between the infant's cheek and gum; parents will be asked to swab a total of five sponges per infant. The infant's mother and father will be asked to provide their own saliva samples by spitting into a funnel connected to small collection tubes. Collection of the saliva samples takes approximately 2-5 minutes per person, but the estimate of burden is 15 minutes per person to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the saliva samples for all centers combined would be approximately 1,444 hours.

Information gathered from both the interviews and the DNA specimens has been and will continue to be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects. The total estimated annualized burden is 2,888 hours.

This request is submitted to obtain Office of Management and Budget (OMB) clearance for three additional years.

There are no costs to the respondents other than their time.

Estimates of Annualized Burden Hours

Respondents	Activity	Number of Respondents	Number of responses per respondent	Avg. burden per response (In hours)
Mothers (interview)	Telephone consent and BD-STEPS questionnaire	1,925	1	45/60
Mothers, fathers, infants (saliva samples)	Written consent for saliva collection and collection of saliva samples	5,775	1	15/60

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